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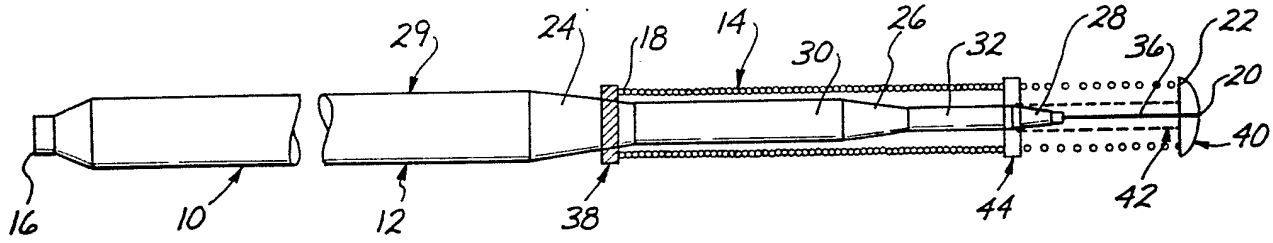

(57) Abstract

A guidewire (10) having a centrally located core wire (12) about which is mounted a single outer helical coil spring (14). The core wire (12) is typically longer than the outer helical coil spring (14), with the helical coil spring and core wire having common distal ends (20, 22). The spring (14) is brazed at both its distal and proximal end to the core wire (12). The distal brazing of the core wire (12) and helical coil springs (14) is rounded. A second small radiopaque helical coil spring (42) is fitted in the distal end of the outer helical coil spring (14) and brazed to the core wire (12) and outer helical coil spring (14) at a location proximal the helical coil spring distal end.

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DUAL COIL GUIDEWIRE WITH RADIOPAQUE DISTAL TIP

BACKGROUND OF THE INVENTION

The present invention is directed at the field of guidewires. Specifically, the present invention concerns a guidewire having a radiopaque tip.

Generally, guidewires include one or more coil springs fixed about a solid or tubular central core wire. Usually, the distal end of the guidewire is shapeable. This shapeability allows the surgeon to bend the distal end before insertion in the vascular system in conformance with the tortuous pathway of the desired vascular system segment through which the guidewire is being manipulated.

Guidewires are principally used for manipulating catheters through a patient's vessels, i.e. blood vessels. One specific application is the proper placement of a catheter in a patient's vascular system for a procedure known as percutaneous transluminal coronary angioplasty (PTCA).

A typical PTCA procedure involves percutaneously inserting a guiding catheter distal tip into the cardiovascular system of a patient and advanced therein until the distal tip thereof is in the coronary artery. A guidewire is introduced through the guiding catheter and advanced into the patient's coronary vasculature until the distal end of the guidewire crosses the lesion to be dilated. A dilatation catheter having an inflatable balloon on the distal portion thereof is advanced over the previously introduced guidewire, with the guidewire slidably disposed within an inner lumen of the dilatation catheter, until the dilatation balloon is properly positioned across the lesion. Once in position across the lesion, the balloon is inflated to a predetermined size

with radiopaque liquid at a relatively high pressure to compress the atherosclerotic plaque of the lesion against the inside of the artery wall. The balloon is then deflated so that the dilatation catheter can be removed and blood flow resumed through the dilated artery.

Examples of guidewire designs are disclosed in U.S. Patent Nos. 4,545,390, issued to Leary on October 8, 1985; 4,538,622, issued to Samson on September 3, 1985; 3,789,841, issued to Antoshkiw on February 5, 1974; 4,815,478, and 4,813,434, both of which issued to Buchbinder et al on March 28, 1989 and March 21, 1989, respectively; 4,922,924, issued to Gamble et al on May 8, 1990; 4,763,647, issued to Gambale on August 16, 1988; 4,846,186, issued to Box on July 11, 1989; and 4,886,067, issued to Palermo on December 12, 1989, with the disclosures of such references concerning the description of the guidewire being incorporated herein by reference.

Numerous workers have devised guidewires to increase the steerability through the coronary system. For example, the tips are made more flexible by terminating the distal end of the core wire short of the distal end of the helical coil spring. A second inner helical coil spring is brazed at one end to the distal end of the core wire and at its opposite end to the distal end of the outer helical coil spring, see Gambale 4,763,647 and Palermo 4,886,067.

Steering of the guidewire through the patient's coronary system is usually accomplished by viewing the guidewire via X-Ray. Visibility of the guidewire is achieved by forming at least a portion of the guidewire from a radiopaque material. This may be accomplished by many different ways. For example, a radiopaque spring is mounted to the end of the guidewire as disclosed in U.S. Patent 4,538,622. Other examples include forming the entire guidewire from a radiopaque spring.

While existing guidewires provide adequate steerability and radiopaqueness, further improvements are desirable.

SUMMARY OF THE INVENTION

The present invention is directed at a guidewire having a centrally located core wire about which is mounted a single outer helical coil spring. The core wire is typically longer than the outer helical coil spring, with the helical coil spring and core wire having common distal ends. The spring is brazed at both its distal and proximal end to the core wire. The distal brazing of the core wire and helical coil springs is rounded. A second small radiopaque helical coil spring is fitted in the distal end of the outer helical coil spring and brazed to the core wire and outer helical coil spring at a location proximal to the helical coil spring distal end.

DESCRIPTION OF THE DRAWINGS

The present invention may be better understood and the advantages will become apparent to those skilled in the art by reference to the accompanying drawings, wherein like reference numerals refer to like elements in the several figures, and wherein:

Figure 1 is a cross-sectional side view of a guidewire in accordance with an embodiment of the invention;

Figure 2 is a sectional, cross section of the distal end of the guidewire of Figure 1;

Figure 3 is a sectional cross section of a distal end of a guidewire in accordance with another embodiment of the invention;

Figure 4 is a further section cross section of a distal end of a guidewire in accordance with a still further embodiment of the invention; and

Figure 5 is a further embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The invention is directed at a guidewire as seen generally in Figure 1 at 10. Guidewire 10 includes a centrally positioned core wire 12 and a outer helical coil spring 14. Centrally positioned core wire 12 and outer helical coil spring 14 have proximal ends 16 and 18, and distal ends 20 and 22, respectively. The distal ends 20 and 22 are commonly located, while the proximal end 18 is located distal of the proximal end 16.

Centrally positioned core wire 12 includes a main segment 29 from which extends multiple reduced diameter segments 30, 32 and 34. Proximally located and tapering to each of the reduced diameter segments 30, 32 and 34 are tapered portions 24, 26 and 28. At the very distal end of the centrally positioned core wire 12 is a tip portion 36. This tip portion 36 is of significantly smaller diameter in comparison to the distally located reduced diameter segment 34. This increases the flexibility of the tip portion 36. Preferably, tip portion 36 is flattened to provide for even greater flexibility. The outer diameters of the various segments of centrally positioned core wire 12, i.e.main segment 29 and reduced diameter segments 30, 32 and 34 is dependent upon the application of the finished guidewire 10. That is, the size of the vessel through which the guidewire 10 passes. This same rationale applies to the diameter or thickness for the tip portion 36.

The lengths of the main segment 29 and each reduced diameter segments 30, 32 and 34, is dependent upon the overall desired length for the guidewire 10. For example, main segment 29 may be 60", with reduced diameter segments 30, 32 and 34 having lengths of 7", 3" and 0.05". The tip portion 36 could be 0.7".

The outer helical coil spring 14 is brazed directly to

centrally positioned core wire 12. Preferably the proximal end 18 of outer helical coil spring 14 is brazed to the first reduced diameter segment 30, as seen at 38, with the distal end 22 brazed to the distal end 20 of centrally positioned core wire 12, as seen at 40. Brazed end 40 is rounded to reduce potential damage to a patient's vessels as the guidewire 10 is manipulated therethrough.

In accordance with the invention, a second radiopaque helical coil spring 42 is fitted in the outer helical coil spring 14. This second radiopaque helical coil spring 42 is positioned at the proximal end 22 and brazed directly to the centrally positioned core wire 12 and outer helical coil spring 14 at a proximal location as seen at 44. The brazing at 44 provides an additional safety joint. That is, some guidewires have the distal end of the core wire terminating before the distal end of the outer helical coil spring.

Breakage of the outer helical coil spring could result in leaving this broken portion of the helical coil spring in the patient upon withdrawal of the guidewire. Attempts to correct this deficiency, as disclosed in Gambale '647 and Palermo '067 include the brazing of the opposite ends of an inner disposed helical coil spring to the distal ends of both the core wire and the outer helical coil spring. This has been suggested as improving the distal tip flexibility. However, breakage of the outer helical coil spring may still result in loss of a portion of the spring due to the lesser strength of the inner helical coil spring. The guidewire of the invention overcomes this deficiency by providing for a secondary brazing 44 of the second radiopaque helical coil spring 42 to both the outer helical coil spring 14 and the centrally positioned core wire 12. The distal end of the second radiopaque helical coil spring 42 is not brazed to the brazed end 40.

The second radiopaque helical coil spring 42 is formed from a suitable material which does not appreciably reduce the overall flexibility of the guidewire 10 distal tip. For example, the second radiopaque helical coil spring 42 may be formed from Rhenium, Tungsten, Tantalum, Platinum or Gold. The outer helical coil spring 14 is typically formed from stainless steel.

The centrally positioned core wire 12 will have a decreasing flexibility from the first reduced diameter segment 30 through the last segment 34. The outer helical coil spring 14 will have the same degree of flexibility along its entire length. The resulting flexibility of the guidewire 10 increases in a direction from the proximal end to the distal end due to the increase in flexibility of the centrally positioned core wire 12 from its proximal to distal ends. The distal tip of the guidewire 10 has a greater flexibility than the remainder of the guidewire 10 due to the flattening of the tip portion 36. Preferably the second radiopaque helical coil spring 42 is formed with adjacent coils spaced apart to provide for greater flexibility. It should be noted that the second radiopaque helical coil spring 42 is only providing the radiopaque feature. This spring 42 need not provide any degree of stiffness to the guidewire 10 distal end so that the coils may be sufficiently spaced apart from adjacent coils to provide the distal end with a high degree of flexibility.

The overall length of the second radiopaque helical coil spring 42 is from about two to four centimeters. As seen in Figure 3, the second radiopaque helical coil spring 42' may in fact extend proximal the brazing 44. The remaining elements of the 10' are essentially the same as the already described guidewire 10, with like reference numeral indicating like elements.

While the described embodiments provide for a single outer helical coil spring 14, other embodiments are

contemplated. This embodiment, seen in Figure 4, replaces a portion of the outer helical coil spring 14 with a multiple helical coil spring arrangement, referred to as a trilayered spring 46. The trilayered spring 46 is formed by inserting one spring inside another, with this arrangement inserted into a third spring. This may be repeated to provide a multiple layered helical coil spring arrangement. One embodiment involves a three layered helical coil spring positioned one inside another as seen in Figure 4 as spring layers 52, 54 and 56. This spring arrangement is purchased from MicroSpring Company of Norwell, Massachusetts under the product name Triplex. A more detailed description of such a trilayered spring 46 is found in U.S. Serial Number 07/318,628, filed on March 2, 1989 entitled TORQUE TRANSMITTER, which description is incorporated herein by reference.

The distal end of the trilayered spring 46, seen generally at 48 terminates proximal to the distal end 20" of the centrally positioned core wire 12. This distal end 48 is typically positioned adjacent the brazing 44". A separate helical coil spring 50 is brazed at one end to the trilayered spring 46 and at the opposite end to the distal end 20 of centrally positioned core wire 12. This helical coil spring 50 may be formed by extending one of the multiple springs to the distal end of the guidewire 10.

The remaining element of the guidewire 10' shown in Figure 4 are the same as those shown in the previous embodiments, with like reference numeral referring to like elements.

A still further embodiment of the invention is seen generally in Figure 5A, at 98. In this embodiment an outer helical coil spring 100 is brazed at locations 102 and 104 to the inner core wire 106. Placed between these two brazing locations 102 and 104, and between the helical spring 100 and the core wire 106 is radiopaque coil 108.

This coil 108 may, or may not be brazed directly to the core wire 106, preferably, coil 108 is freely moveable between the two brazed locations 102 and 104.

Figure 5B is a modification of the guidewire embodiment illustrated in Figure 5A. The distinction is that the outer helical coil spring 100 is replaced with a trilayered spring assembly 110, similar to that described above for the embodiment of Figure 4. The remaining elements of the guidewire 98' are indicated with prime numbers similar to those used in Figure 5A.

While the preferred embodiments have been described, various modifications and substitutions may be made thereto without departing from the scope of the invention. Accordingly, it is to be understood that the invention has been described by way of illustration and not limitation.

What is claimed is:

1. A guidewire comprising:

a core wire having proximal and distal ends;

at least a first helical coil spring fit about said core wire, said helical coil spring having proximal and distal ends, with said helical coil spring proximal end secured to said core wire at a location distal said core wire proximal end, and said helical coil spring distal end secured to said core wire distal end; and

a second helical coil spring dimensioned to fit within said first helical coil spring, said second helical coil spring located at the distal end of said first helical coil spring and secured to said first helical coil spring and said core wire at a location proximal said distal ends of said core wire and coil spring, said second helical coil spring formed from a radiopaque material.

2. The guidewire of claim 1 wherein said second helical coil spring is from two to four centimeters in length.

3. The guidewire of claim 1 further including a rounded tip portion at said distal end of said helical coil spring and core wire.

4. The guidewire of claim 3 wherein said tip portion is secured to said distal ends of said core wire and first helical coil spring.

5. The guidewire of claim 1 wherein said second helical coil spring is formed from Rhenium, Tungsten, Tantalum, Platinum or Gold.

6. The guidewire of claim 4 wherein said second helical coil spring is formed from Rhenium, Tungsten, Tantalum, Platinum or Gold.

7. A guidewire comprising:

a core wire having proximal and distal ends;

at least a first multilayered helical coil spring fit about said core wire, said helical coil spring having proximal and distal ends, with said helical coil spring proximal end secured to said core wire at a location distal said core wire proximal end, and said helical coil spring distal end terminating short of said core wire distal end;

a second helical coil spring fit about said core wire, said second helical coil spring having proximal and distal ends, with said second helical coil spring proximal end secured to said first multilayered helical coil spring distal end, and said second helical coil spring distal end secured to said core wire distal end; and

a third helical coil spring dimensioned to fit within said second helical coil spring, said third helical coil spring located at the distal end of said second helical coil spring and secured to said second helical coil spring and said core wire at a location proximal said distal ends of said core wire and coil spring, said third helical coil spring formed from a radiopaque material.

8. The guidewire of claim 7 wherein said second helical coil spring is from two to four centimeters in length.

9. The guidewire of claim 7 further including a rounded tip portion at said distal end of said helical coil spring and core wire.

10. The guidewire of claim 9 wherein said tip portion is secured to said distal ends of said core wire and first helical coil spring.

11. The guidewire of claim 7 wherein said second helical coil spring is formed from Rhenium, Tungsten, Tantalum,

Platinum or Gold.

12. The guidewire of claim 10 wherein said second helical coil spring is formed from Rhenium, Tungsten, Tantalum, Platinum or Gold.

13. A guidewire comprising:

a core wire having proximal and distal ends;

a first helical coil spring fit about said core wire, said helical coil spring having proximal and distal ends, with said helical coil spring proximal end secured to said core wire at a location distal said core wire proximal end, and said helical coil spring distal end terminating short of said core wire distal end; and

a second helical coil spring fit about said core wire, between said first helical coil and said core wire.

14. The guidewire of claim 13 where said first helical coil spring is a multilayered assembly with at least a first and second helical spring disposed one atop the other.

15. The guidewire of claim 14 further including a third helical fit about said core wire, said third helical coil spring having proximal and distal ends, with said third helical coil spring proximal end secured to said first multilayered helical coil spring distal end, and said second helical coil spring distal end secured to said core wire distal end.

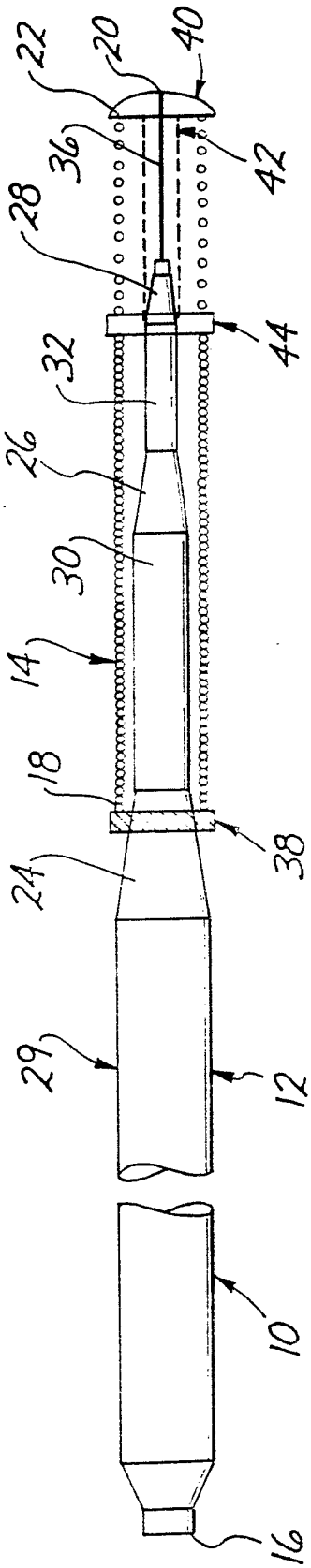

FIG. 1

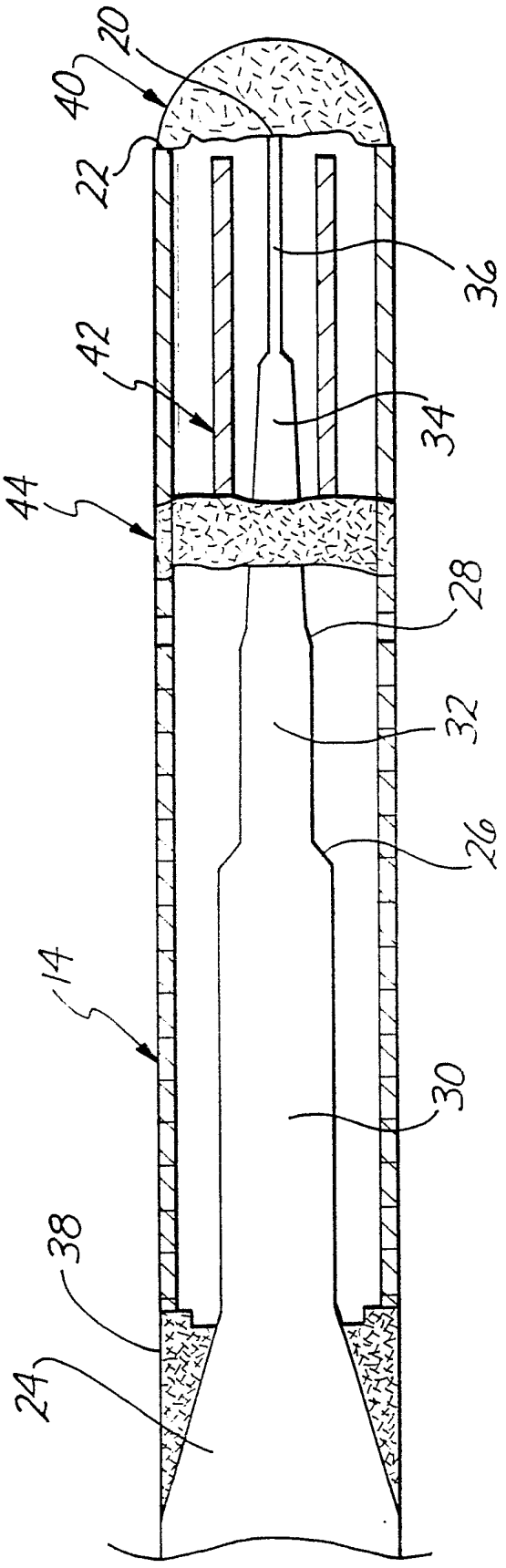

FIG. 2

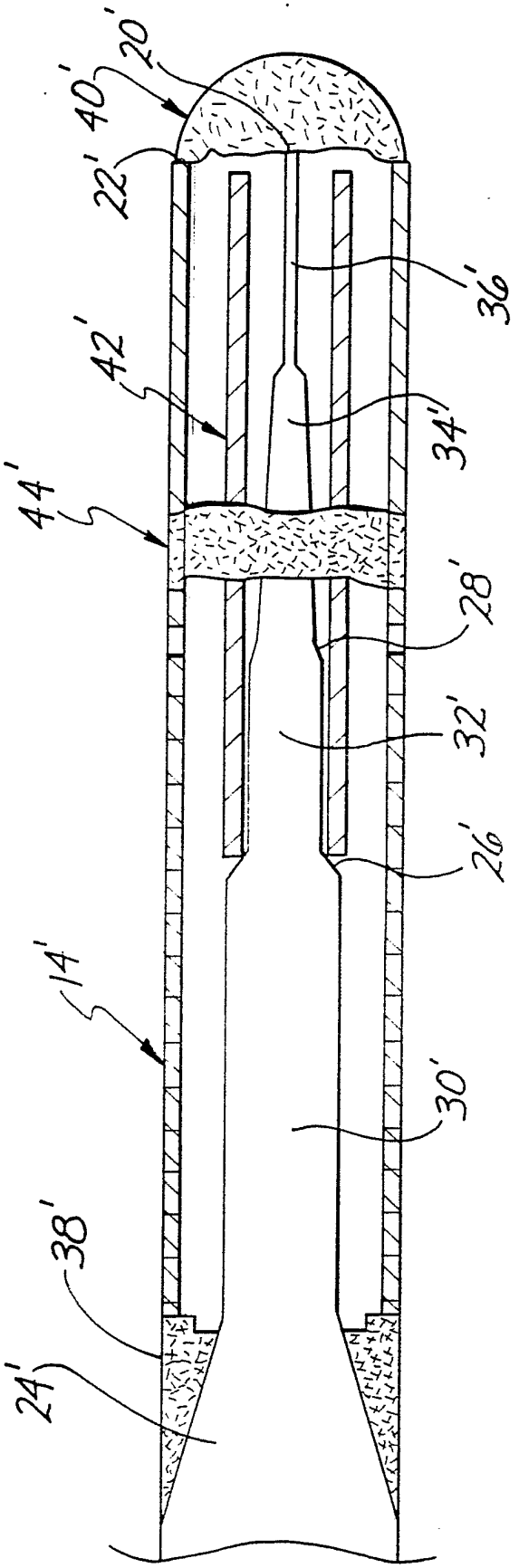

FIG. 3

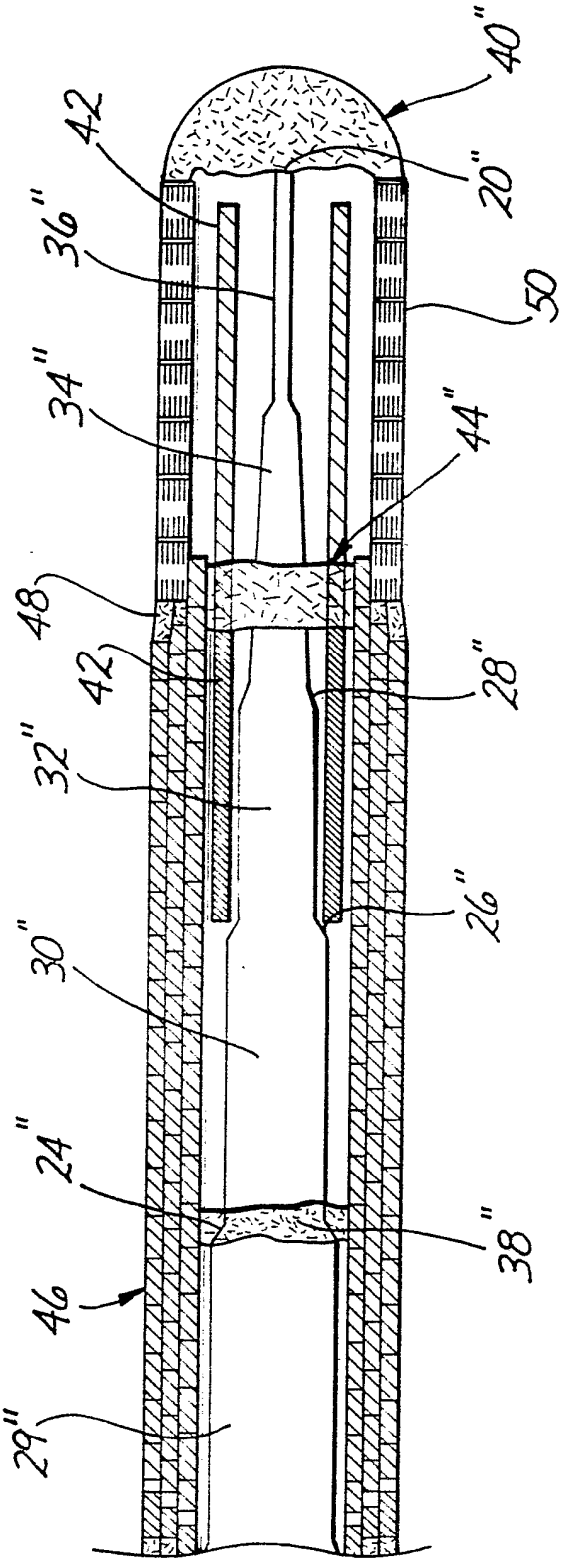

Fig. 4

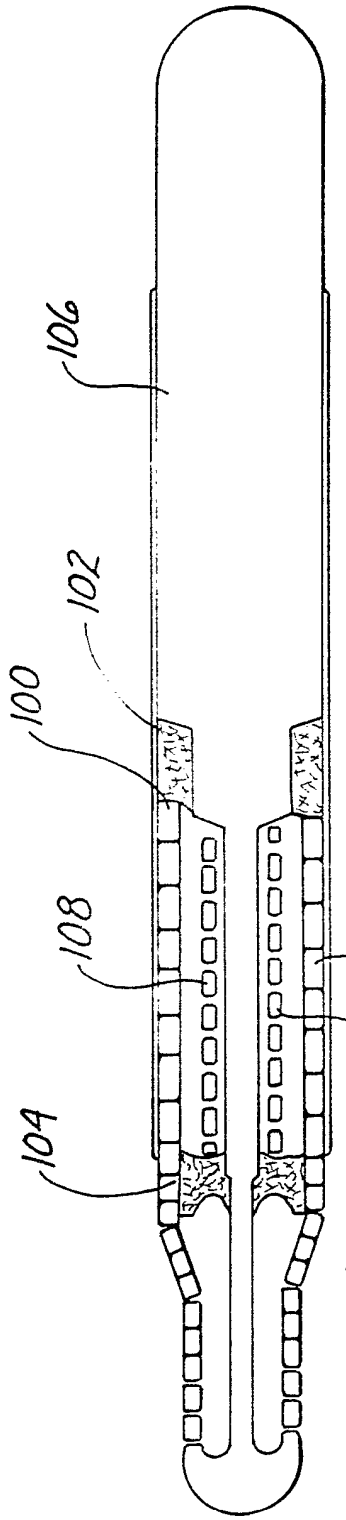

Fig. 5A

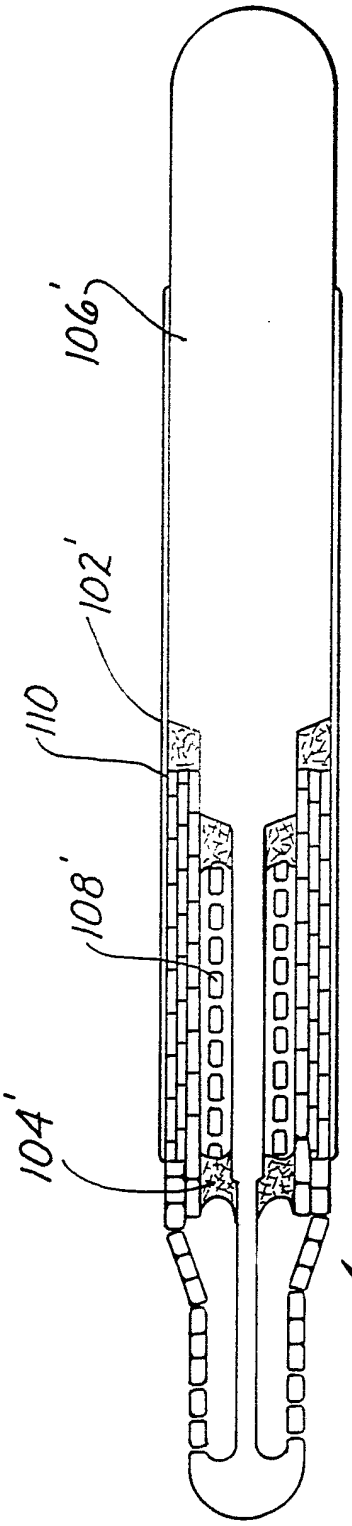

Fig. 5B

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/06132

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M25/01

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	US,A,3 749 086 (KLINE ET AL.) 31 July 1973 see claims; figures	1-6, 13-14
X	WO,A,9 005 486 (BOSTON SCIENTIFIC CORP.) 31 May 1990 see page 5, line 7 - page 6, line 16; figures 1-2	1-3,5, 13-14
X	EP,A,0 259 945 (C.R. BARD, INC.) 16 March 1988 see column 4, line 5 - column 6, line 34; figures 2-3	1-3,5, 13-14

° Special categories of cited documents :[10]

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
06 JANUARY 1992	[illegible]
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9106132 SA 51940

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 06/01/92
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-3749086	31-07-73	None		
WO-A-9005486	31-05-90	CA-A-	2003447	23-05-90
		EP-A-	0435961	10-07-91
EP-A-0259945	16-03-88	US-A-	4719924	19-01-88
		AU-B-	605784	24-01-91
		AU-A-	7688187	17-03-88
		CA-A-	1278233	27-12-90
		JP-A-	63071243	31-03-88